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May 25, 2004

Division of Dockets Management  
Food and Drug Administration,  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket Number 2004N-0115 - Prescription Drug Importation

Included are submitted comments from Flex Products, Inc. relative to technology options available to improve the safety of products in the domestic market as well as to prevent the importation of unapproved or counterfeited drug products.

Should you have any problems or question, please do not hesitate to contact Claire Kammer at (202) 626-8564.

Sincerely,

A handwritten signature in black ink, appearing to read "Chakka" or similar, written in a cursive style.

Claire A. Kammer

**Docket No. 2004N-0115**

**Prescription Drug Importation Task Force**

**Department of Health and Human Services, Food and Drug Administration**

**Comments:**

**Flex Products Inc.**, is the creator and manufacturer of **SecureShift®** -- a technology that utilizes the power and simplicity of **Optically Variable Pigment®**. This unique technology provides a wide range of anti-counterfeit solutions and offers an overt security feature capable of authenticating the safety of our nation's drug supply.

Flex Products, Inc., combines five decades of experience in optical design, interference physics, and high tech manufacturing to produce specialty pigments with outstanding color shifting properties. Colorless flakes comprise the pigment and it seems to the naked eye to change colors, depending on the angle of light hitting it. The thickness of pigment layers and the light angle at which one views a coated object create and manipulate the colors.

Counterfeiters cannot replicate SecureShift® as Flex Products tightly controls manufacturing and distribution, unlike other security features that are both widely produced and distributed. More than 150 global patents protect the technology and manufacturing processes and access is secured due to use of the technology on U.S. currency and the currency of 89 other countries.

SecureShift® pigment integrates easily into security programs and product packaging, offering positive **Authentication**, **Application** flexibility, and **Affordability** to ensure the highest level of security.

- **Authentication** – easy verification by eye of genuine products and a powerful deterrent to counterfeiters. The SecureShift® product can also be forensically identified because of its unique characteristics.
- **Application** – adaptability to a variety of applications, such as labels, packaging, or closures. SecureShift® pigment can be supplied with covert security features and as part of a multi-layered anti-fraud solution.
- **Affordability** – a cost effective solution that seamlessly blends with pharmaceutical labels, packaging or closures. Costs vary, but amount to just 1-2 cents per package. No special equipment or training is required to verify products protected with SecureShift® pigment.

SecureShift® technology provides the security system that allows for adoption of an industry standard overt security feature. It enables the Food and Drug Administration inspectors, drug distributors, pharmacists and individual consumers to authenticate the origin of prescription drugs from credible drug sources. SecureShift® color shifting pigment is available through a secure channel to only legitimate vendors providing a mechanism to identify the drug's origin, even in cases where the drug being supplied is being issued by a foreign source.

*For more information about this request and Flex Products, please contact:*

Mr. Ed Dietrich, Sales and Marketing Director

(707) 547-5690

Flex Products, Inc.

[ed\\_dietrich@flexprod.com](mailto:ed_dietrich@flexprod.com)

1402 Mariner Way

Santa Rosa, CA 95407

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